

TITLE: BLISTER PACKAGE WITH CLOSABLE CAVITIES AND USES THEREOF

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is related to commonly owned co-pending provisional patent  
5 applications Serial Nos. 60/443,677 filed January 29, 2003 and 60/444,492 filed  
February 3, 2003, and claims the benefit of these earlier filing dates.

BACKGROUND OF THE INVENTION

1. FIELD OF THE INVENTION

This invention relates to blister packages having pre-formed cavities for  
10 holding products for display, sale, distribution and use. More particularly, the  
invention relates to blister packages having pre-formed cavities preferably intended  
for holding dosages or selections of materials that have to be used at regular time  
intervals, in different quantities, or over an extended time period, or the like. The  
invention also relates to the use of such packages for the dispensing and use of  
15 materials, particularly medicaments.

2. BACKGROUND ART

Many products these days are displayed and sold in blister packages. Blister  
packages are containers that generally consist of a thin-flat body having at least one  
cavity projecting from at least one side of the body. The cavity is used for holding the  
20 product and the thin-flat body may be used as a support and/or as a medium for  
displaying advertising, decoration or product information. Quite often, the projecting  
cavity is made of a transparent plastic material so that the contents can be observed  
before the package is opened.

A special form of blister package is often used for materials that are required  
25 in dosage or metered form, such as for example medicines. In this case, more than  
one projecting cavity is provided in each package so that the product can be divided  
into two or more doses and the contents of each cavity can be removed and used  
separately from the contents of the other cavities. Perhaps the most well-known  
package of this kind is the one developed for contraceptive pills many years ago  
30 where a separate cavity is provided for each pill so that individual pills can be  
removed and consumed at appropriately-spaced time intervals, e.g. on a daily basis.

In this way, each dosage can be kept fresh, clean and uncontaminated until required for use, and the package acts as a visual confirmation that a dose has been used on time. However, it has been usual in this kind of package to provide an individual dosage form, e.g. a single pill or tablet, in each cavity.

5        In the conventional form of blister packages of this kind, the “blister” is made up of two parts, such as a flat rupturable foil layer sealing the open end of a cavity formed in an adjacent layer. The contents of each cavity can then be removed individually, if the product is sufficiently rigid, by pressing down on the projecting cavity so that the contents, e.g. a pill, bursts through the foil closure.

10      One problem with packages of this kind is that the cavities are not re-usable or re-sealable, once the contents have been removed and the entire package is useless once the final dosage has been removed. Such packages are not convenient for holding several small groups of products, e.g. tablets, that are not all consumed at the same time. Moreover, a package that is suitable for all potential users must be  
15     designed and modifications for different individuals are impossible.

#### SUMMARY OF THE INVENTION

An object of the preset invention is to provide packaging of the blister type that is more effective to use.

Another object of the invention, at least in preferred forms, is to provide a  
20     blister type package that can be used to customize a product for particular individuals or situations.

According to one preferred aspect of the present invention there is provided a package for a product, the package comprising a body formed by layers of packaging material and at least one cavity formed by an outward projection of at least one of the  
25     layers, wherein one of the layers, in a region of the at least one cavity, is provided with a line of weakness or a cut in the material of the layer extending partially around an entrance to the cavity and forming a releasable hinged flap forming an openable and closable lid for the cavity.

Preferably, the body is generally flat and made of two layer of transparent material. By the term "generally flat" we mean that the layers extend from the cavities in an approximate plane or shallow arc. Most preferably, the package has two or more cavities, and ideally 2 to 7 or more.

5 In this way, a product held in the cavity, may be removed simply by releasing the lid formed in the material of the other layer without completely disassembling the entire blister package or destroying individual blisters formed by the cavities.

Preferably, there are two or more cavities per package, each provided with a releasable lid of the type described above.

10 The or each lid preferably has a projection of suitable shape and size to extend partially into the cavity formed from the other layer of material. In this way, the lid can be friction- or compression-fitted into the opening of the cavity, so that the lid may be held securely when closed.

15 Additionally, the lid has an area forming a graspable tab so that the lid may be easily be grasped by the user and pulled away from the remainder of the package to open the cavity. Furthermore, the opposite layer of material beneath the graspable tab may be provided with at least one projection extending from the layer on the side facing the graspable area. This causes the graspable area to stand proud of the layer of material from which it is formed so that it is always readily available to be grasped  
20 by the user.

The lid is preferably square or rectangular in shape and the line of weakness or cut is formed along three sides, leaving the fourth side to form a hinge about which the lid may pivot when released from the cavity.

25 The generally flat body may be used to support or contain printed material indicating the contents of each cavity or the time or date of which the contents of each cavity should be removed and consumed or used. The generally flat body may, of course, be used to support or contain other printed material of an advertising, informative, or decorative nature.

The blister package is most preferably made from a single piece of heat-deformable, preferably transparent, plastic material in which the cavity or cavities and lines of weakness or cut may be made. After this has taken place the material may be folded back on itself along a line and secured around the edges, e.g. by providing the  
5 edges with shapes that fit together by means of a friction fit.

An additional layer of material, e.g. made of paperboard or cardboard or the like, may be sandwiched between the two layers of plastic material (with openings provided appropriately for the one or more cavities) and provided with the intended decorative, informative or advertising material or information.

10 The package of the invention is not only easy to use because the individual lids can be removed from the cavities without disassembling the entire package, but the cavities can be re-closed, for example when each cavity is used to hold several dosages of material (e.g. several pills or tablets) which are not intended to be used or consumed all at the same time. For example, a package containing four re-closeable  
15 cavities of the above kind could be used to hold a product that has to be consumed over four weeks at different dosages for each week. A first cavity could then hold seven tablets of the material at one dosage level and the other cavities could each hold seven tablets of the product at different dosage levels. The user would then remove individual tablets on each day starting with the dosage intended for the first week and  
20 then progressing to the cavity with the tablets intended for the second week.

25 The invention is particularly suitable for packaging four strengths of a product (e.g. a pharmaceutical provided in discrete dosage form, e.g. tablets, pills, capsules, gelcaps and the like) in the same package, or four weeks of dosage. In such cases, it was previously necessary to package the material in four separate bottles or containers. This facilitates those cases where a patient may have to take a regime of treatment requiring different dosages at different times.

According to another aspect of the invention, there is provided a method of distributing a product available in the form of a plurality of discrete units, which method comprises dividing the units into a plurality of groups according to  
30 requirements of a specific user, introducing a different one of the plurality of groups into a different cavity of package of the above type, closing each cavity with the

associated lid, providing the package with instructions regarding the removal of the discrete units from the cavities, and distributing the package to the user of the product. The package of the invention can thus be used for customizing the product to a specific user or group of users, distribution to that user or group and then dispensing 5 of the product while being used by the user or member of the group. The method is particularly suitable for distribution of medicaments that must be taken in regular doses over time, especially where the product is customized to a user by a physician, packaged by a pharmacist according to a prescription from the pharmacist and used by a patient.

10 Thus, the product may be, for example, a medicament in the form of tablets, pills, capsules, or similar discrete units. Many medicaments of this kind are prescribed by physicians in different ways for different patients. For example, a patient may require a different dosage at different times, or different combinations of medicaments at different times. The package of the invention can be used to dispense 15 medicaments of this kind already divided into different dosage forms appropriate for use at the different times.

For example, the drug nefadozone HCl (referred to as Nefazodone or Serazone) is often prescribed for depression. The drug is available in the form of tablets of different dosages (e.g. 50 mg, 100 mg, 200 mg, etc.). Individual patients 20 often require specific treatment regimes. For example, one patient may require one 50 mg tablet every day for a week, then one 100 mg tablet every day for a further week, and so on. Another patient may require a 100 mg tablet once a day for four weeks, etc. In such circumstances, a physician would normally provide several containers, each having tablets of the same dosage strength (all 50 mg, all 100 mg, 25 etc.), and provide the patient with instructions regarding which strengths to use over time. However, this is costly and inefficient and prone to error if patients misunderstand the instructions or choose a wrong container by mistake.

In such circumstances, it is possible to provide a blister package according to the present invention with, say, four cavities, each cavity being intended to hold a 30 supply of tablets for one week, thus making the package suitable for a four week supply. The cavities may be numbered Week 1, Week 2, Week 3, Week 4, respectively. According to the needs of a particular patient, a physician, or more

likely a pharmacist, would fill each cavity with tablets of an appropriate dosage. For example, the first cavity might be filled with tablets of 50 mg strength, the second at 100 mg, the third at 100 mg and the fourth at 200 mg. The patient would then merely consume the tablets from the appropriate for the week of treatment. The tablets may  
5 be removed by raising the lid of the selected cavity, removing one of the tablets, and then closing the lid to keep the remaining tablets secure and sanitary. For a different patient, the cavities might be filled in a different way (e.g. all four containing tables of 50 mg strength).

Not only may the package of the invention be customized in this way, but it  
10 may also be customized for different drugs or other products. For example, a printed card or sheet may be positioned between the layers of the generally flat body. By providing sheets printed with identifying information for a number of different products, a package can be made ready for any one of those products by separating the layers of the generally flat body, inserting a card or sheet appropriate for the  
15 product of interest, and then closing the package so that the card or sheet is secured between the layers. Since the layers are preferably transparent, the information provided on the card or sheet can be viewed through the body portion of the package and information about the product may be viewed.

Accordingly, the package of the present invention is readily customizable and  
20 is perfectly suited for accommodating a new way of distributing products, particularly medicaments, that is customized for individuals that have individual needs. The package not only acts as a means of distributing a product, but also as a means of temporarily storing and dispensing the product until all is consumed. The simplicity and low cost of the package means that it can be discarded after use without adding  
25 unduly to the overall cost of the product.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is top-plan view of a package according to one embodiment of the present invention;

Figure 2 is an underneath plan view of the embodiment of Figure 1;

Figure 3 is a perspective view from above of the embodiment of Figure 1 with the lid of one of the cavities in the raised position;

Figure 4 is a vertical cross-section of the embodiment of Figure 1 taken on the line IV-IV of Figure 1; and

5 Figure 5 is a vertical cross-section of the embodiment of Figure 1 taken on the line V-V of Figure 1;

#### DETAILED DESCRIPTION OF THE INVENTION

A preferred embodiment of the blister package of present invention is shown in Figures 1 through 5 of the accompanying drawings.

10 The drawings show a blister package 10 having a generally flat body 11 formed by two layers 12 and 13 of relatively stiff but flexible material, preferably heat- or impact-deformable, transparent plastic material (for example polyethylene terephthalate or other relatively transparent material). The package 10 has four domed cavities 14 extending outwardly from one of the layers 13 of the material. These  
15 domed cavities form "blisters" for containing and preferably displaying product material. The cavities should preferably be made large enough to hold more than one item, e.g. tablet or capsule, and preferably large enough to hold several such items (e.g. seven items, suitable for daily doses for a week).

On the side of the package 10 opposite the domed cavities 14, the other  
20 layer 12 has lids 15 covering the entrance 16 of each domed cavity 14. The lids 15 are defined by cuts or pre-formed tearable lines of weakness 17 in the layer 12, but these cuts or lines of weakness do not extend fully around each cavity, thus leaving uncut or unweakened sections 18 that may act as a flexible hinge 19 for each  
25 associated lid 15. An advantage of the use of lines of weakness is that the interior of the package may remain completely sealed and sterile, and tampering is immediately apparent in that the lines of weakness will then be torn open and transformed to cuts in the material.

Each lid 15 preferably has a generally planar peripheral portion 20 aligned with (and forming part of) the layer 12 and a central portion 21 that projects inwardly

from the layer 12 and extends for a short distance into the entrance 16 of the domed cavity 14. The central portion 21 is shaped and dimensioned to fit snuggly within the entrance 16 of the associated domed cavity 14, thus forming a secure friction- or compression-fit which holds the lid securely within the opening of the cavity when in  
5 the closed position.

Each lid 15 is provided with an extension forming a tab 22 that can be grasped between the fingers of the user of the package to facilitate removal of a lid 15 from an associated domed cavity 14, thus enabling removal of the contents (not shown) from the cavity.

10 Once a lid 15 has been removed in this way, it is held on the package by means of the flexible hinge 19 and can be repositioned over the entrance 16 of the domed cavity 14 and secured in place once again by means of the friction- or compression-fit.

15 The layer 13 of material from which the domed cavities are formed may be provided with outward projections 25 (preferably of half-moon (hemispherical) shape) beneath the tabs 22 so that the graspable tabs 22 must stand proud of the plane of the layer 12 (see Fig. 4), thus improving their accessibility to the user.

20 The layer 12 of material is also provided with a short, elongated outward projection 26 in the regions of the hinges 19 intended to provide a greater range of movement for the hinges to facilitate the action of the hinges and to reduce the danger that the lids 15 may be torn accidentally from the blister package 10.

25 It will be seen that the lid 15 of each domed cavity 14 may be opened and closed independently of the others so that the contents of one domed cavity 14, or of several domed cavities or even of all domed cavities, may be accessed at the same or at different times.

A layer 30 of thin cardboard, paper or other printable material is provided between the outer layers 12 and 13 of the blister package 10. This layer 30 of material may carry printing or indicia to be seen by the user through the transparent layers 12 and 13. For example, the layer 30 may bear numbers 31 to differentiate the domed cavities 14 from each other and/or to indicate the time periods (e.g. weeks)  
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over which the contents of each cavity may be concealed or used. The printing may alternatively be "Week 1", "Week 2", "Week 3" or "Week 4", or a similar indication.

The card may also contain the name of the product and a decorative logo as well as product information and indication of the source of the product. When the 5 package is to be used for a number of different products, a different layer 30 may be provided for each product with suitable product information and the appropriate one selected when a package is being assembled.

The edges 33 of the blister package 10 may be held together by providing the edges of each layer 12 and 13 with nesting profiles 34 and 34' that mutually engage 10 and hold the layers together by means of a friction- or compression fit. This allows the package to be secured, while allowing it to be disassembled, if necessary.

Alternatively, the edges 33 may be permanently sealed, if desired. Nevertheless, a non-permanent attachment of the edges in the manner described is preferred so that a package made up for one particular product (or a package containing no layer 30) may 15 be opened and the layer 30 replaced or inserted for the first time. This makes the package customizable for a particular product, or changeable from one product to another without difficulty.

The layers 12 and 13 are preferably formed from a single sheet of plastics material that is bent back on itself at fold 36, thus forming a hinge 37. This gives the 20 package a "clam-shell" (book hinge) design or structure.

During manufacturing, the domed cavities 14 are formed by heat molding or stamping in a line on one side of the hinge 37 and the lines of weakness or cuts 17 for the lids 15 are formed by stamping on the other side with the cavities and the lids in proper alignment for correct positioning when the sheet is bent back on itself around 25 the hinge 37. The half-moon projections 25 and elongated hinge 27 are also formed at the same time as the cavities 14 and/or cuts 17, as well as the profiled edges 33. All of this can be done in a single operation starting from a flat sheet of the plastics material. The layer 30 of card (preprinted with desired information or indicia) may be sandwiched within the blister package as the halves of the sheet forming the layers 12 30 and 13 are folded against each other via hinge 37.

In use, the illustrated embodiment may be used to facilitate a novel method of packaging and distributing items, particularly medicaments. For example, a physician may prescribe for a patient a four week course of medication produced in the form of tablets of different strengths. When filling the prescription, the pharmacist selects a 5 package 10 and inserts a layer 30 appropriate for the medicament (showing the name of the medicament, dosage information, labeling for the cavities, decoration, patent and trademark information, etc.). The layers 12 and 13 are then brought together and secured at their edges. The pharmacist then fills each cavity with a dosage form appropriate for one week, using tablets having a strength suitable for the first week in 10 the first cavity, tablets having a strength suitable for the second week in the second cavity, etc. The lids 15 are then closed to temporarily seal the package and a label typical for a medicament container may be applied to the outside or inside of one of the layers 12 and 13. The package is then given to the patient, who will select tablets from the first cavity during the first week, the second cavity during the second week, 15 etc. This facilitates distribution and proper use of the product.

Although a preferred embodiment of the invention has been described in detail above, it will be apparent to persons skilled in the art that other embodiments and variations may be employed without departing from the scope of the invention.